K121268

Summary of safety and effectiveness

DEC 2 0 2012

In accordance with Section 513 (1) of the SMDA as defined in 21CFR part 807.3 this summary is submitted to obtain Pre-Market 510 (K) notification.

1. Submitter / Contact person.

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2. **Manufacturer**

Wandy Rubber Industrial Co., Ltd (Reg Nr. 3003749270)
48, Lane 392, Fu Teh 1st RD
Xi-Zhi dist 221, New Taipei City, Taiwan, R.O.C.
Tel: 886 2 2694 3184 Fax: 2 2694 4574

3. Name of Device

Trade name	:	Wandy Dispersive Electrode
Classification name :	:	Electrosurgical, Cutting, Coagulation & Accessories
Panel	:	Plastic and General Surgery
Common name	:	Grounding Pad
Regulation	:	878.4400 Class II
Product Code	:	ODR

4. Legally marketed Predicate Device

K100686 Conmed Corp Macrolyte Dispersive Electrode

5. Device Description

Wandy Dispersive Electrode is designed to provide a safe return path Electrosurgical current between Generator, to active electrode and to patient without cord.
And able to use to any patient if full skin contact available.
non sterilized and to use only one time.

The surface of the conductive area is covered with a Bio-compatible Hydro-gel and the surface of the non-conductive area made of PE Foam and Texture Fabric is covered with Medical grade adhesive for maximum skin adhesion. This device are non sterilized and one time use only, available 3 sizes with various shape for Adult / Pediatric

Manufactured in accordance with both mandatory and voluntary standards

IEC 60601-2.2 Medical Electrical equipment part 2-2 Ed 5/9 2009-02
General requirement for safety
Performing, Bench test done by manufacturer accordance,
IEC 60601-2-2: 2006-59.104.5 / 104.79b(b),(c) / and attached report
ISO10993-5 Invitro Cytotoxicity 2002
10 Skin Sensitization / Irritation 2009

6. Intended use

Wandy's Dispersive Electrode is intended use to the patient during Electrosurgical procedures to provide a path for RF current to leave the patient and return to the Generator

7. Technological Characteristic.

Proposed device are single use, non-sterilized with connector to use with any Electrosurgical device. And designed with PE form or Textile fabric on non conductive area and self-adhesive Hydro-gel on conductive area, with Rectangle shape.
This device has same indication for use, same output power (300W, 700mA @615 ohms for less than 60 seconds)as predicate cleared electrode device in the market.

7. Bio-Compatibility

The biological safety of used components of Wandy's Dispersive Electrode was conformed by the guidance of ISO 10993-1: Biological Evaluation of Medical Device

Test Report attached

8. Safety and Effectiveness.

Wandy's Dispersive Electrode is substantially equivalent to several predicate devices that have already been cleared in respect to Intended use, Main function, Technology, Principal operation and performance.

So, it does not raise any additional concerns regarding safety and effectiveness.

Wandy's Rubber Industry will include in this summary with updates on any other information deemed seasonally necessary by the FDA.

End of summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Bio-Med USA, Incorporated
% Mr. Young Chi
President
111 Ellison Street
Paterson, New Jersey 07505

Re: K121268
Trade/Device Name: Wandy Dispersive Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: ODR
Dated: November 15, 2012
Received: November 20, 2012

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use statement

510 (K) number : 121268

Device name : Wandy's Dispersive Electrode

Indication for use : Wandy's Dispersive Electrode is intended use to the patient during Electrosurgical procedures to provide a path for RF current to leave the patient and return to the Generator

Prescription use _____xx_____ **or/and Over the Counter use**_____
(Part 21 CFR 801 Sub part D) **(Part 21CFR 801 Sub part C)**

Please do not write below line-continued an another pages if needed

Concurrence of CDRH, office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Surgical Devices
510(k) Number: K121268